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SEP - 8 1997

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REQUIREMENT FOR INFORMATION

This is in response to the application for patent term extension under 35 U.S.C. § 156, filed July 7, 1997.

The requested information must be submitted within TWO (2) MONTHS from the mail date of this letter. Failure to respond may result in a delay in the processing of the application. Extensions of time under 37 CFR 1.136(a) are NOT permitted.

In order to determine whether a patent is eligible for patent term extension, it is necessary to determine whether the patent to be extended claims the approved product or a method of use of the approved product. In order to assist the Office in this determination, documentation of the description of the product Cook GRII™ Coronary Stent is requested. For example, if a part of the PMA supplement, or an amendment thereto, describes the Cook GRII™ Coronary Stent, then a copy of that description would be of assistance. Furthermore, any available product circulars describing the Cook GRII™ Coronary Stent would also be of assistance.

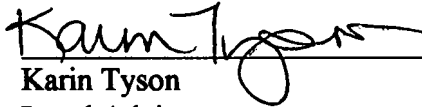
Correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

A handwritten signature in dark ink, appearing to read "Karin Tyson", is written over a horizontal line.

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: Cook GRIT™ Coronary Stent